AdAlta
next generation protein therapeutics

ASX Announcement

AdAlta 2019 AGM: Chair and CEO addresses

MELBOURNE Australia, 26 November, 2019: AdAlta Limited (ASX: 1AD), is pleased to release a copy of the Chairman's address and CEO's report that will be delivered to shareholders today at the Company's 2019 Annual General Meeting.

Address to shareholders, by Paul MacLeman, Non-Executive Chairman

I will now present a brief Chairman's address:

The past year has seen AdAlta make significant progress with its lead therapeutic i-body, AD-214, which is being developed for the treatment of Idiopathic Pulmonary Fibrosis. The Company has also achieved a number of other key commercial milestones.

We commence our first-in-class human clinical trial next quarter and will reach a critical inflection point at that time, moving from a pre-clinical to a clinical stage company. Interest from big pharma in our i-body platform was evidenced in the recently signed deal with global medical technology and diagnostics firm, GE Healthcare. The Company also identified early opportunities for pipeline development during the year.

These value driving achievements have been made possible by a highly capable team. I'd like to thank our past CEO, Sam Cobb for the many years of committed leadership that she provided AdAlta. This meeting also provides the opportunity to formally welcome Dr Tim Oldham, who recently joined us to take AdAlta through the next phase of its life. Tim will present the CEO's report shortly, which in the interests of good governance will also be available via the ASX and AdAlta websites in scripted format.

Now we will turn to the business of the meeting.

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Address to shareholders by Dr Tim Oldham, CEO and Managing Director

This document can be read in tandem with the CEO's presentation which has also been lodged with the ASX and is available via the Company's website at www.adalta.com.au.

Good afternoon ladies and gentlemen. Thank you for attending our Annual General Meeting this afternoon – my first since becoming CEO just a month ago. I would like to thank you for your ongoing support of AdAlta. I would also like to thank Sam Cobb, our founding CEO and my predecessor, for her service and commitment, without which AdAlta would not have the growth opportunities that so attracted me to the Company. My final thanks is to the Board for entrusting me with the challenge and responsibility of realising those opportunities for our shareholders.

This afternoon, I'd like to give you a brief overview of my background as well as a summary of AdAlta's strategy and operations, before closing with some reflections on my first month in the role.

[Progress to slide: Adalta overview]

So, just a brief recap of our company. Adalta is generating a promising new class of protein therapeutics, known as i-bodies, for treating a wide range of human diseases, including fibrosis.

And our lead internal program, AD-214 is due to commence a human Phase 1 clinical trial in early 2020, a significant "coming of age" event for the Company as I will discuss later.

[Progress to slide: Introducing new CEO, Tim Oldham PhD]

As I'm new to many of you, I thought I'd share with you some of my background and talk about the opportunity I see ahead of us as we move toward what will be a key inflection point for the company.

I trained in chemistry and law at ANU in Canberra, before completing my PhD at Imperial College in London. After five years working for McKinsey & Company, I have spent almost 20 years in the pharmaceutical and biotechnology industry, working in Australia, Europe and Asia and with additional experience of the US market. Most of my career has been

spent building new businesses, either within larger companies or small companies focussed on commercialising biotechnology innovation. I have also served on the Board of several ASX listed companies.

Bringing novel or complex therapeutics to market has been both a feature and a passion throughout my career. My interest in therapeutic proteins began when I first joined the industry, leading the then Mayne Pharma's effort to enter the biosimilar, or generic biologics, field and I was involved in the development of some of the very first biosimilars, together with the regulatory pathways that enabled these to be approved for marketing. More recently I have been involved with the development and manufacturing of cell and gene therapy products including as CEO of Cell Therapies, and the development of bi-specific antibodies, another approach to improving the effectiveness of antibody drugs, that first made me aware of AdAlta and cell and gene therapies.

[Progress to slide: AdAlta (1AD) Investment Summary]

I joined AdAlta because I believe it is a well-positioned company and a great investment proposition:

- First, it is a genuine platform technology with a distinct competitive advantage. AdAlta is one of the subset of Australian biotech companies where the underlying technology has the potential to generate multiple therapeutic products. The underlying i-body platform technology has a competitive advantage in its ability to access multiple biological targets that are intractable to traditional approaches. This means we can become a sustainable company that over time generates value from diversified product pipeline, rather than a company dependent on the success or failure of a single product: AdAlta is so much more than AD-214 and pulmonary fibrosis.

- Having said that, AD-214 is important and the second reason that attracted me to AdAlta. Aside from addressing an important medical need with poor existing options in multiple indications or diseases (attractive in its own right), AD-214 is about to commence clinical trials. Taking its first product into clinical trials is a major "coming of age" event for a biotech company. It is the first time that the Company's pre-clinical development data is reviewed by independent parties (in our case ethics committees) who will determine whether we have done everything necessary to minimise the risk of harm, demonstrate a reasonable basis for effectiveness, and that there is no remaining

meaningful way to learn more about our product than administer it to humans. For AdAlta, this step demonstrates not only confidence in AD-214, but in our entire platform. Successful completion of Phase 1 will demonstrate safety of not only AD-214 but also the potential of other platform products to be safe in humans. It is very exciting to be joining the Company at such a pivotal time.

- For reasons of resources, money and focus we will only be able to develop in house a small fraction of the possible products our platform can produce. So my third reason for joining AdAlta is that the Company has already demonstrated, with the recently announced GE deal, the ability to partner its platform to expand the number of products that can be developed from it. This adds further value to the Company.

- And finally, the team was an important part of my decision. We clearly have a well credentialled drug discovery team, led by CSO Mick Foley, who understands our platform and how to leverage it to find binders to the difficult targets we aspire to hit. The ability to manufacture our products is a rarely spoken about but mission critical part of any biologics development program that cannot be taken for granted. It is important to me that we have protein development skills and experience such as those possessed by COO Dallas Hartman. And we have an experienced Board and advisory network who are willing to roll-up their sleeves and devote significant time to the Company. I believe my skills and experience are very complimentary to this team, spanning strategy, partnering and business development, product design, therapeutic manufacturing, corporate governance and investor relations.

[Progress to slide: AdAlta business model and strategy to create value]

Now let's recap the business model by which we will realise value from the investment shareholders have made and are making in our Company.

Our i-bodies (left hand side and centre of this slide) are well suited to drugging novel and challenging targets. Many of these, including the large families of G-protein coupled receptors (GPCRs) and ion channels are involved in multiple biological signalling pathways. They have often only been accessible using small molecules to date, but really need to be engaged with the specificity of an antibody to achieve the specific biological effect required to both modify disease and minimise side-effects. In other words, we do not have good drugs to these targets today.

Our overarching objective is to use our i-body platform to produce a new family of i-body based drugs and diagnostics acting on these challenging targets to address significant unmet medical needs (as shown by the bar across the centre of this slide). We do this in two ways.

First, as illustrated on the top of this slide, we will discover and develop a pipeline of our own drug candidates. We plan to develop these candidates up to key clinical value inflection points, potentially in multiple indications, prior to out-licensing to a large pharma partner to complete development and commence sales of the product. Under this scenario, we would expect to earn major upfronts, milestones and royalty payments. AD-214 is the first of these products.

The bottom section of this slide illustrates the second model where, as with the deal we announced in September with GE Healthcare, we will use our i-body platform to identify targets of commercial interest to a pharma partner. In most cases, this would lead us to co-develop a product and this kind of work would attract research fees and royalties. While the overall returns to AdAlta will be lower, these products are developed at essentially no cost to us.

[Progress to slide: AdAlta pipeline]

This slide shows a picture of our pipeline as it currently stands. You can see we have AD-214 positioned in both the first and second rows of the chart as while we're moving it into the clinic focused on Idiopathic Pulmonary Fibrosis, we also have, and continue to generate a good deal of data which shows its broad applicability in other fibrotic diseases.

We have also highlighted two other different types of targets in early discovery, MCP-1 and TRPV4, to demonstrate the applicability of the i-body platform beyond GPCRs and of course our collaborations with Excellerate Bioscience to enhance our GPCR characterisation capabilities and with GE.

I am pleased to advise today that we have screened our i-body libraries and obtained binders to 20 separate targets, more than half of which are the GPCRs and ion channel targets that are a major focus of big pharma today. This clearly demonstrates the wide potential of our technology.

Target selection is an important skill for any good platform company, and this is a process which takes time. As we move AD-214 into the clinic, we are in the process of selecting the next products to evaluate as drug candidates and plan to provide a strategic update in February that will include our initial targets.

[Progress to slide: AD-214 has broad application in treating fibrosis]

Our data in several animal models of disease and with human tissue suggests that AD-214 can improve fibrosis and inflammation across a range of fibrotic diseases, such as Wet-Age Related Macular Degeneration in the eye, Non-alcoholic steatohepatitis (NASH) in the liver and chronic kidney disease. We also know that fibrotic diseases are known and recognized in many more organs.

We believe therefore that AD-214 could have application in multiple indications – again we will report on our indication extension plans in our February strategy update.

[Progress to slide: Market opportunity for IPF]

As shareholders will be aware, AdAlta is focusing the development of AD-214 on idiopathic pulmonary fibrosis, or IPF. This is a clinical indication with significant unmet medical need.

In IPF patients, injury and inflammation in the lungs causes a build-up of collagen. This causes the lungs to stiffen, and eventually, patients will die from an inability to breathe. There are 300,000 people living with the condition across the western world with an median life expectancy of just 3.8 years. 40,000 die from the disease each year.

The only two existing drugs on the market today only work for roughly 35% of patients and are accompanied by significant side effects which cause many patients to cease therapy within about 18 months. Combined, they still sold US$1.5b in 2017 and are projected to reach $3b by 2025 (right hand side of this slide). While this is a potentially large patient population, it also qualifies as an orphan disease, meaning new products can obtain preferential regulatory review, shortening development times.

[Progress to slide: AdAlta's place in the IPF treatment landscape]

We see a real opportunity to do a better job with a uniquely positioned AD-214:

- The approvals of pirfenidone and nintedanib created confidence that drugs could be developed for IPF. As discussed, neither of these are optimal and the unmet need is still significant. To illustrate the unmet need, just after we announced our non-human primate toxicology results that cleared the way for our first human clinical trials of AD-214, I received an email from the carer of a patient in the US asking whether we could make AD-214 available to her under an expanded access program (regretfully this is not appropriate or possible at this stage of development)

- There are a relatively small number of other products in development, and they help define the pathway and study design for patient clinical trials

- And AD-214 is the only drug we are aware of targeting the CXCR4 GPCR receptor to modify disease. This gives us the advantage of being first in class with our therapeutic and may partially protect us from competition as multiple drug classes are likely to be required to successfully manage IPF.

[Progress to slide: AD-214 novel treatment for fibrosis – lung]

This slide exemplifies what we are hoping to achieve in patients. Here you can see the effects of our anti-CXCR4 i-body in recognised IPF disease model: mice treated with a compound called bleomycin. On the left is normal lung tissue and in the middle, we see the build up of collagen in diseased tissue (stained in blue) – this is a hallmark of fibrosis.

On the right, treatment with anti-CXCR4 i-body has significantly reduced the collagen levels and restored normal lung architecture. (Note that this data was generated with AD-114, the predecessor to AD-214 that uses the same i-body and different half-life extension technology.)

[Progress to slide: AD-214 safe in 4-week toxicology study]

Before we test AD-214 in humans, we needed to complete pre-clinical toxicology studies. We have now completed three non-human primate studies, most recently a Good Laboratory Practice (GLP) study to evaluate safety and toxicology prior to initial human studies.

AD-214 was well tolerated and shown to be very safe. The findings were all in line with our previous studies and expectations.

We are in the process of evaluating the data to draw further findings relating to pharmacokinetics and pharmacodynamics and expect to release those over the next couple of months.

[Progress to slide: AD-214 development: key milestones]

Now we are focused on the next steps ahead of our Phase 1 human clinical trial commencing early next year.

We announced recently that we had successfully manufactured GMP-grade drug substance for the trial. This is a critical step that cannot be taken for granted and was the first time we had manufactured AD-214 at this scale. The drug substance is currently in the final stages of formal release testing and will shortly be manufactured (dispensed) into vials suitable for patient administration. We will also be making placebo vials.

We're also finalising contracts for clinical trial vendors and working on finalising the study design and other documents necessary for ethics approval. Specifically, while the conventional approach for a Phase I trial would be for us to dose healthy human volunteers, we are exploring ways to obtain some data on how AD-214 performs in IPF patients as part of our Phase I trial program. Having more data will add further value to the discussions we have with big pharma.

[Progress to slide: GE Healthcare licensing deal – i-body platform]

We've also been focused on securing collaborations, which provide additional opportunities to leverage the i-body platform, and externally validate its potential for novel drug discovery.

We secured such a collaboration in September with global medical technology and diagnostics firm, GE Healthcare.

Under the deal, AdAlta will screen its novel i-body library in order to identify i-bodies targeting an enzyme called Granzyme B that GE can use as diagnostic imaging agents. The agreement could be expanded to additional targets. What's interesting is

that we have shown with this deal that bigger organisations are interested in using our technology for a wide range of applications.

We will see our first revenues come onto the balance sheet in the December quarter in the form of the £100,000 up-front payment that was invoiced to GE and initial research fees.

These first revenues are another significant milestone in the growth of your company.

The deal is the first in a range of therapeutic and diagnostic partnerships that we are looking to develop.

[Progress to slide: Market benchmarks]

AdAlta does not expect to develop its products all the way to commercialisation – rather, as mentioned earlier, we expect to partner with large pharma companies to complete late stage development. It is important therefore that deals are being done in the indication that we are pursuing (fibrosis), with the drug format we are using (broadly micro-antibodies) and for the targets we are focused on (GPCRs). This chart shows that there is indeed an active and valuable deal making environment in all three areas, with many valuable deals are being completed during Phase I.

Of particular note, in the IPF space, two partnering deals have been done in the last five months. It was announced in July that Boehringer Ingelheim would license Bridge Biotherapeutics' phase I asset for a €45m upfront and up to €1.1b in milestones and royalties. This deal occurred while the drug was in phase I and was said to be about 12 months away from commencing a phase II trial. Earlier this month Roche acquired Promedior primarily for a Phase II IPF asset for $390m upfront and around $1b in milestone payments.

We are talking with and will continue to have discussions with a range of potential partners for AD-214. While these deals can happen early, it is our responsibility to assess each opportunity at face value – the early ones may not be the best ones – and to plan to continue development independent of deals, so we move forward with the commitment to evaluate all opportunities and determine what represents best value for shareholders. It is important also to remember that these companies were progressing multiple products in a parallel which supported confidence. The value of products being in the clinic from the platform is significant.

We've said before we like the Ablynx example of building a company that has multiple products in the pipeline, creating multiple recurring revenue streams and sustainable value for shareholders. This remains our long-term focus.

[Progress to slide: Significant 2019 achievements]

Looking back, 2019 has been a significant year for AdAlta.

We've completed manufacturing of AD-214 – as I mentioned earlier, this was a key and critical step for your company. Engineering and manufacturing first in class drugs is not easy work, but we are very pleased with the manufacturing outcomes.

We completed our non-human primate toxicity studies and reported that data in line with expected timeframes.

We also successfully negotiated and executed the licensing deal with GE which now gives us the opportunity to work with a major global player to develop new diagnostic tools for cancer imaging.

The peer reviewed scientific journal, mABs published research on the ability to customise the half-life (or the duration in which it can stay in the circulation), during the period. We formed a research collaboration with UK based Excellerate Biosciences, which we hope will help us accelerate the characterisation and selection of GPCR focused i-body drug candidates.

Finally, we made a number of key appointments. Dr Ros Wilson joined the Board as Non-Executive Director during the period. Ros has spent a lot of time in the pulmonary space and has recent clinical trial experience which she can bring to bear as the company moves to start the AD-214 trial.

Of course, there was a change of guard with Sam Cobb moving on from the CEO role after 12 years and having built a tremendous company. I was subsequently appointed in October and you will be the judge of the quality of that appointment!

[Progress to slide: Financial position]

On to our financials.

We have a reasonable cash position of $7.59m as at September 30, which is an increase on $5.56m in previous quarter.

We are fortunate to be overweight with institutional support for a company of our size, with funds like Yuuwa Capital, Platinum Asset Management, Private Portfolio Managers and others on the register. We are grateful of their ongoing support and I will share more about my initial interactions with them shortly.

The share price has been through a tough time over the past few months. We are focused on hitting our goals and communicating them to the market and to potential partners. As I stand here now, we are closer to the clinic than we've ever been before, the deal landscape remains just as vibrant and we now have new opportunities moving into our pipeline. In my view, AdAlta makes a very compelling investment right now.

[Progress to slide: Financial results]

Our financial results on a cash basis are shown on this slide. The left-hand table shows our financial year cash movements for the past two financial years and the right hand chart shows our quarterly inflows and outflows over the past five quarters and forecast for this quarter.

Our cash outflows have steadily increased over the past five quarters and prior year as a direct result of increased expenditure on AD-214 manufacturing process development, pilot production and GMP production and expenses associated with non-human primate toxicity studies. These costs of developing our technology have been financed through new capital raising and R&D Tax Incentive Scheme refunds.

Shareholders would be aware that in October we forecast high cash outflows for the December quarter, which includes a number of one-off costs relating to GMP manufacturing of AD-214, and this will be our largest cash outflow on a quarterly basis this financial year. We are currently funded into Phase I clinical studies for AD-214. In addition to our health cash balance at 30 September, we are working on several cash management strategies to maximise the results we can obtain from our Phase I program with currently available resources.

[Progress to slide: first month reflections]

During my first month I have been focused on 3 priorities (that will remain the focus of the next 3 months):

1. Advance AD-214 into a first clinical trial
2. Execute the initial milestones of the GE contract
3. Develop a strategic roadmap for growing your Company

I have summarised my reflections during my first month on this slide. The key themes are:

- First, that your Company is on track to achieve the critical transition from pre-clinical stage to clinical stage; and

- Second, that there are significant growth opportunities that could be exploited in the near to mid-term. These include further clinical development of AD-214 and indication expansions, expected process and platform improvement opportunities that will reduce manufacturing costs and improve discovery efficiency (and potentially generate new intellectual property) and obviously new product candidate opportunities that can be discovered using our platform.

- Third, that major shareholders are generally supportive of expanding development activity in an appropriately measured way

- And finally that your Company is “on the radar” screen of potential partners from around the globe. I have been pleased by the number of inbound enquiries, including from companies new to the AdAlta story, that we have received in the past month.

Essentially my incoming assumptions about status and opportunities have been validated. We have lots of work still to do, and the results will not all come overnight, however I am confident that as we continue to achieve our operational milestones, we will continue to cement the foundation of the Company and earn the right to substantially expand our activities and with it the value of your shareholdings.

[Progress to slide: FY20 news flow]

Toward the end of the 2019 calendar year, we plan to provide further information regarding the cash management strategies we are working on to stretch our current cash reserves.

Then we move into 2020, which will be the most significant in your company's history. In Q1 calendar 2020, we will provide further analysis of the recent toxicology studies, where we will focus on pharmacokinetic and pharmacodynamic results.

In February, we plan to provide a strategic update which will outline our AD-214 clinical development strategy and introduce an initial slate of priority drug targets for which we hope to discover i-body based drug candidates.

Soon after that, we will commence our first in human, AD-214 phase I study, with all patients in the initial single ascending dose component due to receive AD-214 or placebo in the first half of 2020.

As mentioned previously, moving from being a pre-clinical company to a clinical one is a major milestone for any biotech company. When you're in the clinic with an IPF asset, you're well and truly on the map of big pharma. The data from this series of Phase I studies will play a key role in any commercial discussions.

[Progress to slide: AdAlta Limited (ASX:1AD) Summary]

Summing up, the year ahead brings AdAlta closer to significant commercial inflection points than its ever been before.

We have a platform technology with the potential to generate multiple pipeline products and partnerships. We're looking at additional expansion opportunities through partnering.

The AD-214 Phase I trial program will commence shortly and escalate our position in the global IPF development landscape.

Between a healthy cash balance and our cash management strategies, we are funded into Phase I clinical studies for AD-214.

And we've got the team (internal and external) to execute.

[Progress to last slide]

Thank you for your time this afternoon and for your ongoing support.

Notes to Editors

About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain, that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors and ion channels that are implicated in many serious diseases.

AdAlta is currently preparing for its phase 1 clinical studies for its lead i-body candidate, AD214. The clinical program is expected to commence in early 2020 following completion of the current toxicity study, clinical trial design finalisation and manufacture of clinical product. AD214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need. The Company is also in collaborative partnerships to advance the development of its i-body platform. It has recently announced an agreement with UK-based research organisation, Excellerate Bioscience to collaborate on an undisclosed target of commercial interest and an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta plans to continue further drug discovery and development directed towards other drug targets and diseases.

Further information can be found at: www.adalta.com.au.

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